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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Applicants proposed amendment if entered would require further consideration on the basis that it would result in at least an additional rejection under 112 second paragraph based upon indefinitness. This rejection would be based upon the recitation" that includes a mutation at W550" It would be unclear as to what applciants were referring to in reference to "that includes". Is it residues 13-555 of SEQ ID NO:26, or the encoded polypeptide? Further support for the newly claimed subject matter, depending upon exactly what that is, has not been eluded to or found in applciants specification at the time of filing and thus would result in a possible rejection based upon new matter.

DETAILED ACTION

Applicant's amendment of claims 1-16, 18-31 and 66, in the paper of 11/16/2010, is acknowledged. Claims 1-66 are still at issue and are present for examination.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-18, 65 and 66, to a polynucleotide and (1) polynucleotide sequences encoding for polypeptides having 80% identity to residues 13-555 of SEQ ID No:26, wherein said polypeptide has at least one mutation, at position W550 (position 827 of the Taq polymerase wild-type); and (1) polynucleotide SEQ ID No:21 (at least claims 1-6, 10, 12, 14-18, 65 and 66 readable thereon), is acknowledged.

Applicants' arguments filed on 11/16/2010, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 2, 7-9, 11, 13, 19-64 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

Claims 1, 3-6, 10, 12, 14-18, 65, 66 are objected to because of the following informalities: Claims 1- 6, 10, 12, 14-18, 65, 66 contain non elected subject matter in the form of mutations in addition to W550, which applicants previously elected.

Appropriate correction is required.

Specification

The previous objection of the disclosure for Figure 6a, b and Figure 7 containing amino and or nucleic acid sequences which require a sequence identifier, is withdrawn on the basis that these figures do not contain amino or nucleic acid sequences.

The disclosure is objected to because of the following informalities: On page 34 of applicants specification applicants lists a number of embodiments drawn to a number of monoclonal phages. Applicants specification is unclear as to what each of these monoclonal phages contains or how they were generated. (See also below rejection of claim 65 based upon 112 second paragraph).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 65 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Previously it was indicated that claim 65 is indefinite in the recitation "An insert contained in a phage selected from the group consisting of I-3168, 1-3169, 1-3170, 1-3171, 1-3172, 1-3173, 1-3174, 1-3175, 1-3176 and 1-3158 in CNCM on February 27, 2004." because it is unclear as to exactly what it is that applicants are claiming.

Applicants have amended the claim to recite "A monoclonal phage selected from the group consisting of a phage deposited under accession number I-3168, 1-3169, 1-3170, 1-3171, 1-3172, 1-3173, 1-3174, 1-3175, 1-3176 and 1-3158 in CNCM on February 27, 2004." Applicants have not commented as to the rejection beyond applicants amendment .

Applicants amendment of the claim and applicants complete argument is acknowledged and has been carefully considered, however, is not persuasive in overcoming the rejection on the following basis. Applicants have now amended the claim to read on those "monoclonal phages" deposited under the referred to accession numbers. The claim remains indefinite in that it is unclear as to what the monoclonal

phages deposited under the referred to accession numbers are on the basis that applicants specification does not clearly describe each of these deposits with regard to what they are and how they were made. While page 34 of applicants specification refer to each of these deposits, it remains unclear as to what they are and how they were made. Applicants specification in referring to the various deposits refers to "SJL", however, it is unclear what "SJL" is or what it refers to. Thus while it appears that applicants have deposited the various "monoclonal phages" the claim remains unclear as to exactly what each of the claimed monoclonal phages are.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 65 and 66 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office action as it applied to previous claims 1-6, 10, 12, 14-18, 65 and 66. In response to this rejection, applicants have amended claims 1-16, 18-31 and 66, and traverse the rejection as it applies to the newly amended claims.

Applicants do not traverse the rejection beyond applicants amendment of the claims.

Applicants amendment of the claims and applicants complete argument is acknowledged, however, is not persuasive in overcoming the rejection of claim 66.

Claim 65 and 66 remain rejected under this statute on the basis that while applicants have enabled the claimed monoclonal phages by depositing them under the Budapest Treaty in an acceptable depository, it remains that applicants have not adequately described the claimed "monoclonal phages" (See also above rejection under 112 second paragraph). The specification fails to describe the claimed monoclonal phages by any identifying structural characteristics or properties, for which no predictability of structure or function is apparent (See also above rejection under 112 second paragraph). Given this lack of structural and/or functional characteristics or properties as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1, 3-6, 10, 12, 14-18, 65 and 66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for that polynucleotide encoding a thermostable polypeptide, wherein said polynucleotide comprises the nucleic acid sequence of SEQ ID NO:21, does not reasonably provide enablement for any polynucleotide which encodes a thermostat polypeptide comprising an amino acid

sequence having a mere 95% identity to residues 13-555 of SEQ ID NO: 26, wherein said polypeptide has at least one mutation at a position W550, and wherein said polypeptide has DNA polymerase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action as it applied to previous claims 1-6, 10, 12, 14-18, 65 and 66. In response to this rejection, applicants have amended claims 1-16, 18-31 and 66, and traverse the rejection as it applies to the newly amended claims.

Applicants traverse this rejection on the basis that the rejection is moot based upon the above amendments and applcaints submission that products which encode or which exhibit thermostable polymerase activity may be identified.

Applicants amendment of the claims and applicants complete argument is acknowledged and have been carefully considered, however, are not considered persuasive for the reasons previously made of record and for those reasons repeated herein.

It is pointed out that applicants have amended applcaints claims so that the claimed polynucleotide is no longer required to encode a polypeptide which has DNA polymerase activity, thus sufficiently broadening the claimed genus to include those polypeptides which do not have polymerase activity. Thus one of skill in the art would not know how to use a great many of the encompassed polynucleotides having 95% identity to residues 13-555 of SEQ ID NO: 26, wherein said polypeptide has at least one

mutation at a position W550, and wherein said polypeptide has an undefined activity. While the claims rejected under this section of U.S.C. 112, first paragraph, place structural limits on the claimed polynucleotides there is no functional limitation on the claimed polynucleotides or the encoded polypeptides. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to that that polynucleotide comprising the nucleic acid sequence of SEQ ID NO:21.

The specification does not support the broad scope of the claims which encompass all modifications of any polynucleotide which encodes a any polypeptide comprising an amino acid sequence having at least 95% identity to residues 13-555 of SEQ ID NO: 26, wherein said polypeptide has at least one mutation at a position W550, and wherein said polypeptide has DNA polymerase activity because the specification does not establish: (A) regions of the protein structure which may be modified without effecting functional activity and (B) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the desired activity claimed and the fact that the relationship between the sequence of a peptide and its tertiary structure

(i.e. its activity) are not well understood and are not predictable (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to arrive at the majority of those polynucleotides of the claimed genus encoding any polypeptide.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of any polynucleotides which encodes a polypeptide comprising an amino acid sequence having at least 95% identity to residues 13-555 of SEQ ID NO: 26, wherein said polypeptide has at least one mutation at a position W550. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 66 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 7,417,133. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 15 of U.S. Patent No. 7,417,133 drawn to a monoclonal phage of CNCM

I-3171 and CNCM I-3176, anticipates instant claim 66 as newly amended to a monoclonal phage selected from the group consisting of I-3168, 1-3169, 1-3170, 1-3171, 1-3172, 1-3173, 1-3174, 1-3175, 1-3176 and 1-3158 in CNCM (See also above rejection under 112 second paragrqaph). It is noted that this rejection is based upon applicants previous amendment of the claims on 11/16/2010.

Remarks

No claim is allowable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.